510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k053034

B. Purpose for Submission:

New device

C. Measurand:

Tetrahydrocannabinol

D. Type of Test:

Qualitative lateral flow immunochromatographic test

E. Applicant:

Acro Biotech, LLC

F. Proprietary and Established Names:

Acro Rapid THC Urine Test

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.3870, Cannabinoid Test System

2. Classification:

   Class II

3. Product code:

   LDJ

4. Panel:

   91, Toxicology

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   Acro Rapid THC (Marijuana) Urine Test is a lateral flow, rapid immunoassay for the qualitative detection of tetrahydrocannabinol in human urine at a cutoff of 50 ng/mL. The test is used to obtain a visual qualitative result and is intended for laboratory use only.

   This assay provides only a preliminary result. Clinical consideration and professional judgment must be applied to a drug test result, particularly in evaluating a preliminary positive result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectroscopy (GC/MS) analysis is preferred.

3. Special conditions for use statement(s):

   For prescription use

4. Special instrument requirements:

   Not applicable, the device is a visually-read single-use device

I. Device Description:

The device consists of a strip within a cassette. (See "Test Principle" below.)

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Ameditech Immutest Drug Screen THC

2. Predicate 510(k) number(s):

   k011813

3. Comparison with predicate:

   The intended use and general methodology is similar for both devices.

K. Standard/Guidance Document Referenced (if applicable):

None referenced

L. Test Principle:

From the package insert: Acro Rapid THC (Marijuana) Urine Test is based on the principle of competitive immunochemical reaction between an immobilized drug-protein conjugate and THC, which may be present in the urine sample for limited binding sites of a labeled THC antibody. The test contains a nitrocellulose membrane strip pre-coated with drug-protein conjugate in the test region and a wicking pad containing colored antibody-colloidal gold conjugate. During the test, the urine sample is allowed to migrate upward and hydrate the antibody-colloidal gold conjugate. The mixture then migrates along the membrane chromatographically by capillary action to the immobilized drug-protein band in the test region. When drug is absent in the urine, the colored antibody-colloidal gold conjugate and immobilized drug-protein bind specifically to form a visible line in the test region (test line). When THC is present in the urine sample, it will compete with the drug-protein conjugate for the limited antibody binding sites. The test line will be less intense with increasing drug concentration. When the drug is present in sufficient concentration in the urine sample, it will fill the limited antibody binding sites, which will inhibit attachment of the colored antibody-colloidal gold conjugate to the drug-protein conjugate in the test region. Therefore the presence of the test line indicates a negative result for THC and the absence of the test line indicates a preliminary positive result for THC.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

   a. Precision/Reproducibility:

   The reproducibility of the device was evaluated at multiple biotech company sites, and one hospital site. Each site tested the device against masked urine controls containing 0, 25, 37.5, 62.5, 75 and 100 ng/mL THC. Similar performance was observed at the various sites. Composite results are shown below:

Results with samples containing 0 ng/mL	Results at 25.0 ng/mL	Results at 37.5 ng/mL	Results at 62.5 ng/mL	Results at 75.0 ng/mL	Results at 100.0 ng/mL
0+, 60-	0+, 60-	15+, 45-	44+,16-	60+, 0-	60+, 0-

b. *Linearity/assay reportable range:*

Not applicable. The assay is intended for qualitative use.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Procedural controls are included in the test strip of the device. A line appearing in the control region (C) is internal procedural control; it confirms sufficient specimen volume was added to the device.

External control materials are not supplied with this test; however the labeling includes a recommendation that external positive and negative controls be tested to ensure proper kit performance. Users should follow local, state and federal guidelines for testing QC material.

d. Detection limit:

See the Precision/Reproducibility Section (1a), above.

e. Analytical specificity:

The following structurally related compounds were serially diluted (1:1), added to drug-free urine and observed to yield positive results at the concentrations listed below.

Compound	**Concentration in ng/mL**
11-nor-Δ -9-THC-9-COOH	*50*
11-hydroxy-Δ -9-THC	*1,000*
Δ-8-tetrahydrocannabinol	*5,000*
Δ-9-tetrahydrocannabinol	*5,000*
Cannabinol	*10,000*
Cannabidiol	*>100,000*

The compounds shown below were added to a pool of urine samples containing THC at 25 ng/mL, and 100 ng/mL. At concentrations of 100 ug/mL the substances listed below did not alter the expected results.

Acetaminophen Acetone	*Hemoglobin*
Albumin	*Ibuprofen*
Ampicillin	*(+/-)-Isoproterenol Ketamine*
Ascorbic Acid	*Levorphanol*
Aspartame	*Lidocaine*
Aspirin	*(+)-Naproxen*
Atropine	*Niacinamide*
Benzocaine	*Nicotine*
Bilirubin	*(+/-)-Norephedrine*

Caffeine *Chloroquine* *(+/-)-Chlorpheniramine* *Creatine* *Dexbrompheniramine* *Dextromethrophan* *Diphenhydramine* *Dopamine* *(+/-)-Epinephrine* *Erythromycin* *Ethanol* *Furosemide* *Glucose* *Guaiacol Glyceryl Ether*	*Oxalic Acid* *Penicillin-G* *Pheniramine* *Phenothiazine* *1-Phenylephrine* *β Phenylethylamine* *Procaine* *Quinidine* *Ranitidine* *Riboflavin* *Sodium Chloride* *Sulindac Theophylline* *Tyramine* *4-Dimethylaminoantipyine* *(1R, 2S)-(-)-N-Methyl-Ephedrine*

f. Assay cut-off:

The identified cutoff concentration for marijuana metabolites (50 ng/mL) is the one recommended by the Substance Abuse and Mental Health Services Administration (SAMHSA). Analytical performance of the device around the cutoff is described in Section 1.a., above.

2. Comparison studies:

a. Method comparison with predicate device:

Negative specimens: 70 urine specimens were donated by sixty self-declared non-drug users and were determined negative by testing with the predicate device. In addition, 60 urine specimens, pre-screened by GC/MS for THC, were evaluated. Results are shown below.

	Ameditech Immutest	GC/MS		
New Device	Negative	Near Cutoff Negative (– 50% to cutoff)	Near Cutoff Positive (ranging from the cutoff to +50% of the cutoff)	Positive (> +50% of the cutoff)
Positive	0	3	7	37
Negative	70	7	3	3

b. Matrix comparison:

Not applicable; this device is only for use with urine samples

3. Clinical studies:

   a. Clinical Sensitivity:

   Not applicable. Clinical studies are not typically provided for this type of device.

   b. Clinical specificity:

   Not applicable.

   c. *Other clinical supportive data (when a. and b. are not applicable)*:

   Not applicable

4. Clinical cut-off:

   Not applicable.

5. Expected values/Reference range:

   Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.